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September 23, 2003

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BY HAND

Ms. Maria Simeone
Docket Clerk for the Honorable Patti B. Saris
United States District Court
for the District of Massachusetts
One Courthouse Way
Boston, MA 02210

Re: *In re: Pharmaceutical Industry Average Wholesale Price Litigation MDL No. 1456*

Dear Ms. Simeone:

Per our conversation today, I am enclosing a date stamped copy of the Defendant-Specific Memoranda in Support of the Motion to Dismiss the Amended Complaint of Suffolk County that was filed on September 15, 2003 in the above referenced matter. As we discussed, this document does not seem to appear on the on-line court docket (PACER). Please also note that this document was e-filed on September 15, 2003 on Verilaw.

Very truly yours,

A handwritten signature in cursive script that reads "Laura L. Phair".

Laura L. Phair
Paralegal

Encl.

Cc: John Therien, Esq.

RICHT COURT
ICT OF MASS.

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

2003 SEP 15 P 5:33

IN RE PHARMACEUTICAL INDUSTRY
AVERAGE WHOLESAL PRICE
LITIGATION

) MDL No. 1456

) Civil Action No.

) 01-CV-12257-PBS

FILED
CLERK'S OFFICE

THIS DOCUMENT RELATES TO:

*County of Suffolk v. Abbott Laboratories, Inc.,
et al.,*
E.D.N.Y. Case No. CV-03-229

) Judge Patti B. Saris

**DEFENDANT-SPECIFIC MEMORANDA
IN SUPPORT OF THE MOTION TO DISMISS**

The following defendants submit the attached Defendant-Specific Memoranda in Support of the Motion to Dismiss: Abbott Laboratories, Inc.; Amgen, Inc.; AstraZeneca Pharmaceuticals LP; Aventis Pharmaceuticals; Bayer Corporation; Berlex Laboratories, Inc.; Biogen, Inc.; Eli Lilly and Company; Forest Pharmaceuticals, Inc.; MedImmune, Inc.; Merck & Co., Inc.; Novartis Pharmaceuticals Corporation; Pfizer Inc., Pharmacia Corporation and Pharmacia & Upjohn, Inc., Purdue Pharma L.P.; Reliant Pharmaceuticals, LLC; Sanofi-Synthelabo, Inc.; Schering-Plough Corporation; TAP Pharmaceutical Products, Inc.; Warrick Pharmaceuticals Corporation; and Wyeth.

CERTIFICATION PURSUANT TO LOCAL RULE 7.1

Counsel for defendants hereby certify that they have conferred with plaintiffs in a good faith attempt to narrow or resolve the issues presented by these memoranda.

**Schering-Plough Corporation
Warrick Pharmaceuticals Corporation**

By their attorneys

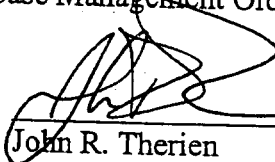


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John R. Therien (BBO#651185)
Ropes & Gray
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Boston, MA 02110
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Dated: September 15, 2003

CERTIFICATE OF SERVICE

I hereby certify that on September 15, 2003, I caused a true and correct copy of the Defendant-Specific Memoranda in Support of the Motions to Dismiss to be served on all counsel of record by electronic service pursuant to Case Management Order No. 2 entered by the Honorable Patti B. Saris in MDL 1456.


John R. Therien



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DISTRICT COURT
DISTRICT OF MASS.

2003 SEP 15 P 5:30

September 15, 2003

FILED
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COPY

Clerk for Civil Business
United States District Court
for the District of Massachusetts
U.S. Courthouse
One Courthouse Way, Suite 2300
Boston, MA 02210

Re: In re: Pharmaceutical Industry Average Wholesale Price Litigation MDL No. 1456

Dear Sir/Madam:

Enclosed for filing please find the following:

- (1) Defendants' Motion to Dismiss the State of Montana's Second Amended Complaint and the State of Nevada's Amended Complaint; and
- (2) Appendix of Exhibits.

Please date-stamp the enclosed copy of this cover letter and return it to our messenger. Thank you.

Very truly yours,

John R. Therien

cc: All counsel of record (via Verilaw)

DISTRICT COURT
DISTRICT OF MASS.

UNITED STATES DISTRICT COURT FOR
THE DISTRICT OF MASSACHUSETTS

2003 SEP 15 P 5:31

IN RE PHARMACEUTICAL INDUSTRY
AVERAGE WHOLESALE PRICE
LITIGATION

FILED
IN CLERK'S OFFICE
MDL No. 1456

THIS DOCUMENT RELATES TO:

State of Montana v. Abbott Labs, Inc., et al.,
02-CV-12084-PBS

*State of Nevada v. American Home Products
Corp., et al.*, 02-CV-12086-PBS

Civil Action No. 01-CV-12257-PBS

Judge Patti B. Saris

COPY

**DEFENDANTS' MOTION TO DISMISS THE STATE OF MONTANA'S SECOND
AMENDED COMPLAINT AND THE STATE OF NEVADA'S AMENDED COMPLAINT**

Pursuant to Federal Rules of Civil Procedure 9(b) and 12(b)(6), the undersigned Defendants respectfully move this Court jointly for dismissal of all claims against them in the State of Montana's Second Amended Complaint and the State of Nevada's Amended Complaint. The grounds for this motion are stated in: (1) the Consolidated Memorandum in Support of Defendants' Motion to Dismiss, in which nearly all defendants join; and (2) the individual memoranda of law filed by some defendants, which they have submitted to address issues specific to them or issues that were not included in the Consolidated Memorandum. This Motion is submitted on behalf of all defendants who have been properly served.

WHEREFORE, for the reasons set forth in the memoranda described above, the Defendants respectfully request that the Court grant their motion to dismiss the claims against them in the State of Montana's Second Amended Complaint and the State of Nevada's Amended Complaint and enter an Order:

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- a. dismissing all claims in the aforementioned Complaints with prejudice;
and
- b. providing such other and further relief as the Court deems just and proper.

Respectfully submitted,

**ON BEHALF OF LISTED DEFENDANTS
IN THE ABOVE-CAPTIONED ACTIONS,**

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DATE: September 15, 2003

*Counsel for SmithKline Beecham Corp., d/b/a
GlaxoSmithKline*

ON BEHALF OF:

ABBOTT LABORATORIES

AMGEN, INC.

APOTHECON, INC.

ASTRAZENECA PHARMACEUTICALS LP

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

IN RE PHARMACEUTICAL INDUSTRY
AVERAGE WHOLESALE PRICE
LITIGATION

) MDL No. 1456

) Civil Action No.

) 01-CV-12257-PBS

THIS DOCUMENT RELATES TO:

*County of Suffolk v. Abbott Laboratories, Inc.,
et al.,*

) Judge Patti B. Saris

E.D.N.Y. Case No. CV-03-229

**DEFENDANT-SPECIFIC MEMORANDA
IN SUPPORT OF THE MOTION TO DISMISS**

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**Schering-Plough Corporation
Warrick Pharmaceuticals Corporation**

By their attorneys

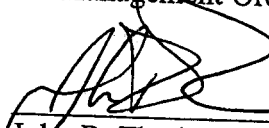


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Dated: September 15, 2003

CERTIFICATE OF SERVICE

I hereby certify that on September 15, 2003, I caused a true and correct copy of the Defendant-Specific Memoranda in Support of the Motions to Dismiss to be served on all counsel of record by electronic service pursuant to Case Management Order No. 2 entered by the Honorable Patti B. Saris in MDL 1456.


John R. Therien

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#1

**UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS**

**IN RE: PHARMACEUTICAL INDUSTRY
AVERAGE WHOLESAL PRICE
LITIGATION**

MDL NO. 1456

THIS DOCUMENT RELATES TO:

CIVIL ACTION: 01-CV-12257-PBS

County of Suffolk v. Abbott Laboratories, Inc., et al.

Judge Patti B. Saris

**ABBOTT LABORATORIES, INC.'S SEPARATE
MEMORANDUM OF LAW IN SUPPORT OF ITS MOTION
TO DISMISS SUFFOLK COUNTY'S AMENDED COMPLAINT**

Suffolk County asserts claims against Abbott Laboratories, Inc. ("Abbott") as to only two products: Depakote® and Kaletra®. Both are brand name drugs. As to these drugs, Suffolk County makes no effort to provide any of the specificity necessary to comply with this Court's May 13, 2003 ruling regarding the minimum pleading requirements plaintiffs must meet. Thus, in addition to the reasons stated in the defendants' consolidated memorandum, Suffolk County's claims against Abbott should be dismissed because:

- ◆ Suffolk County alleges no fraudulent acts by Abbott with respect to Depakote® and Kaletra®.
- ◆ Suffolk County does not allege any competitors for Depakote® and Kaletra®.
- ◆ The State of New York had actual knowledge of the market prices for all drugs reimbursed by Medicaid, including Depakote® and Kaletra®.

To the extent that Suffolk County purports to assert claims as to any drugs other than Depakote® and Kaletra®, those claims also should be dismissed in accordance with the Court's May 13, 2003 Order.

Suffolk County's Amended Complaint mirrors in many respects the State of Montana's Second Amended Complaint and private plaintiffs' Amended Master Consolidated Complaint ("AMCC"). Abbott has filed memoranda in support of motions to dismiss both of those cases. Rather than repeat *verbatim* the arguments set forth in those other memoranda, Abbott will summarize below how those arguments apply to Suffolk County's Second Amended Complaint. In all other respects, Abbott will incorporate arguments made in prior Abbott briefs in an effort to conserve space and judicial resources.

I. Suffolk County Does not Identify Any Fraudulent Conduct as to Depakote® and Kaletra®

The specific allegations asserted against Abbott are scant. Suffolk County accuses Abbott of participating in two schemes: One to inflate AWP, the other to misreport Best Price. In both cases, the facts alleged as to Abbott are insufficient.

As to the scheme to manipulate AWP, Suffolk County does not describe a single act by Abbott or its agents in furtherance of the alleged fraud. Instead, Suffolk County alleges simply that the AWP for Depakote® and Kaletra® are between 25% and 29% higher than a number described only as “Suffolk’s Estimated True AWP.” Suffolk County never describes what this so-called “True AWP” represents, how it was calculated, or how Suffolk County collected the information on which any calculations were based. This differential between AWP and an imaginary “True AWP” constitutes the only allegations made against Abbott relating to Depakote® and Kaletra®. *See* Am. Compl. ¶¶ 125-132 (Abbott-specific allegations). Suffolk County never even alleges what it paid for Depakote® and Kaletra®. Instead, Suffolk County describes settlements of cases having nothing to do with Depakote® and Kaletra®. *See id.* ¶¶ 130-131.

Suffolk County’s Best Price allegations are even more sparse. Neither Abbott nor its drugs are mentioned at all in connection with this alleged fraud involving the Medicaid Rebate Program. *See* Am. Compl. ¶¶ 84-91. Suffolk County never alleges what rebates were paid for Depakote® and Kaletra®, nor what those rebates should have been.

These bare-bones allegations do not satisfy Rules 9(b) and 8(a). First, the allegations contravene this Court’s instruction that plaintiffs “clearly and concisely” describe the fraud that they are alleging. *In re Pharmaceutical Indus. Average Wholesale Price Litig.*, 263 F. Supp. 2d 172, 194 (D. Mass. 2003) (hereinafter “*AWP Litigation*”). *See* Tr. of Jan. 13, 2003 Hearing on

Mot. to Dismiss, at 74 (“You’ve got to meet 9(b) requirements. You’ve got to particularize exactly what drugs, *exactly what the fraud is*, which plaintiffs paid for what drugs.”) (emphasis added). As to both AWP and Best Price, Suffolk County falls far short of this requirement.

Second, Suffolk County’s allegations fail to explain how any statements by Abbott could be construed as fraudulent. *See Suna v. Bailey Corp.*, 107 F.3d 64, 68 (1st Cir. 1997) (requiring plaintiff to explain why statements were fraudulent); *United States ex rel. Gublo v. NovaCare, Inc.*, 62 F. Supp. 2d 347 (D. Mass. 1999) (dismissing Medicare fraud case under Rule 9(b) because the plaintiff failed to allege why or how the defendant’s price representations were fraudulent). In fact, Suffolk County identifies no statements at all by Abbott, although it implies that Abbott reported an AWP for Depakote® and Kaletra®. More importantly, Suffolk County nowhere explains why these reported AWPs would be fraudulent, noting only the existence of a “spread”. As Abbott explained in its motion to dismiss Montana’s Second Amended Complaint, such conclusory allegations cannot suffice.¹

For all of these reasons, all claims against Abbott should be dismissed for failure to plead fraud with specificity pursuant to Rules 9(b) and 8(a).

II. Suffolk County Does not Allege Any Competitors for Depakote® and Kaletra®

Suffolk County contends that defendants inflated AWPs in order to “motivate providers to distribute the drugs with the highest reimbursement rate.” Am. Compl. ¶ 10. As to Abbott, however, Suffolk County does not identify any competitors for Depakote® and Kaletra®. Suffolk County likewise never explains whether the providers who purportedly made a profit from the “spread” have any role in the decision to prescribe Depakote® and Kaletra®. In short, Suffolk

¹ See Abbott’s Individual Memorandum in Support of its Motion to Dismiss the State of Montana’s Second Amended Complaint (filed Sept. 15, 2003) (hereafter “Abbott Mont. Mem.”), 4-5.

County has failed to allege facts sufficient to support their contention that “marketing the spread” (*id.*) is possible for Depakote® and Kaletra®. As described fully in other memoranda filed with this Court on pending motions to dismiss, these pleading deficiencies require the dismissal of Suffolk County’s claims against Abbott.²

III. The State of New York Knew as a Matter of Law That AWP Exceeded Market Prices

As set forth in detail in the defendants’ consolidated memorandum, the State of New York was fully aware that AWP exceeded market prices, yet still chose to reimburse certain Medicaid-covered drugs by reference to AWP. In addition to the public record establishing the nature of AWP, however, New York had actual knowledge of market prices by virtue of its participation in the Medicaid Rebate Program. As Abbott describes in its memorandum in support of the motion to dismiss Montana’s Second Amended Complaint, the states’ rebates bear a mathematical relationship to Average Manufacturer’s Price (“AMP”). *See* 42 U.S.C. § 1396r-8(c). AMP is by definition the average price at which manufacturers sell their drugs to wholesalers for distribution to retail pharmacies. 42 U.S.C. § 1396r-8(k)(1). Thus, by performing a simple calculation, New York has always had the ability to determine that the reimbursement it was paying exceeded the average price of drugs in the market. Because Suffolk County had actual knowledge of facts inconsistent with its claims of fraud, its claims fail as a matter of law.

² *See* Abbott’s Individual Memorandum in Support of its Motion to Dismiss the AMCC (filed Aug. 1, 2003), 5; TAP Pharmaceutical Products Inc.’s Individual Memorandum in Support of its Motion to Dismiss the AMCC (filed Aug. 1, 2003), 4-5. *See also* Abbott Mont. Mem., 5; TAP Pharmaceutical Products Inc.’s Individual Memorandum in Support of its Motion to Dismiss the State of Montana’s Second Amended Complaint (filed Sept. 15, 2003), 4.

IV. This Case is Limited to the Drugs Listed in Exhibits A and B

Suffolk County must specify by name the drugs as to which it alleges fraudulent manipulation of AWP's. *AWP Litigation*, 263 F. Supp. 2d at 194. As a result, the claims asserted by Suffolk County are limited to Depakote® and Kaletra®, the only two Abbott drugs identified in Exhibits A and B of its Amended Complaint. To the extent that Suffolk County purports to assert claims as to any other Abbott drugs, those claims should be dismissed.³

V. Conclusion

For the foregoing reasons, as well as those stated in the defendants' consolidated memorandum and those individual defendants' memoranda that apply to Abbott, this Court should dismiss Suffolk County's Amended Complaint as to Abbott.

³ Depakote® and Kaletra® are brand name drugs. To the extent that the Court declines to dismiss claims relating to unnamed drugs, Abbott incorporates herein the arguments asserted in its motion to dismiss Montana's Second Amended Complaint with respect to (a) AWP claims arising from multiple-source drugs and (b) rebate claims arising from non-innovator multiple-source drugs. See Abbott Mont. Mem. at 1-4.

Respectfully Submitted,

Dated: September 15, 2003



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#2

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

IN RE PHARMACEUTICAL INDUSTRY
AVERAGE WHOLESALE PRICE
LITIGATION

) MDL No. 1456

) Civil Action: 01-CV-12257-PBS

) Judge Patti B. Saris

THIS DOCUMENT RELATES TO:
County of Suffolk v. Abbott Labs., et al.,
(E.D.N.Y. No. CV-03-229)

MEMORANDUM IN SUPPORT OF
AMGEN INC.'S INDIVIDUAL MOTION TO DISMISS
COUNTY OF SUFFOLK'S AMENDED COMPLAINT

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Defendant Amgen Inc. ("Amgen") moves to dismiss the amended complaint filed by County of Suffolk ("Suffolk") because it fails to allege any specifics in support of its claim that Amgen was involved in the so-called AWP "scheme." The amended complaint is long on conclusions and short on specifics. Despite clear direction from this Court in related matters, Suffolk does not, for instance, allege even a single specific purchase of any Amgen product by any Suffolk County resident; does not allege specific prices or explain why any prices are fraudulent; and does not allege any specific sales or marketing practices at Amgen that it contends are improper. Unlike many other defendants, Amgen is not alleged to be the subject or target of government investigation relating to AWP. Nor is it alleged to be the subject of any government audit relating to AWP or identified as a recipient of any Congressional subpoena or other request for documents relating to AWP. Suffolk has simply lumped Amgen in with an entire industry that is under attack, hoping ultimately to find some support for its claims through discovery. Rule 9(b) requires more.

Suffolk's claims relating to Amgen's EPOGEN® also should be dismissed. This products – one of only three Amgen products identified in the amended complaint – is not even reimbursed based upon AWP. Because EPOGEN® is not reimbursed based upon AWP, its price cannot be manipulated, as Suffolk has alleged.

I. Suffolk's Allegations against Amgen Fail Under Rule 9(b).

Suffolk must, at a minimum, "clearly and concisely allege with respect to each defendant: (1) the specific drug or drugs that were purchased from defendant, (2) the allegedly fraudulent AWP for each drug, and (3) the name of the specific plaintiff(s) that purchased the drug." *In re Pharmaceutical Indus. Average Wholesale Price Litig.*, 263 F.Supp.2d 172, 194 (D. Mass.

2003).¹ Suffolk has not done so. It has not alleged with any specificity why or how the AWP for Amgen's products are fraudulent. Merely asserting that Suffolk reimbursed a provider based upon a published AWP and comparing that AWP to a made up number – "Suffolk's Estimated True AWP" – that is neither defined nor explained, is not enough. Indeed, far from providing any specifics of a supposed fraud as required by Rule 9(b)², Suffolk does not provide even a single actual price at which any Suffolk County resident purchased any Amgen product.

Instead, Suffolk offers up only the most conclusory allegations that Amgen:

- "Reported, or caused to be reported," inflated AWPs, without providing a single example of a supposedly "correct" price and offering instead its own "estimated true" price (AC at ¶ 138)³;
- controlled or set the AWPs for its products "through direct communications with the compendia" without providing a single example of any such a communication by Amgen that supposedly controlled or set an allegedly overstated or incorrect AWP, much less the requisite date, time or place of any such communication (AC at ¶ 145); and,

¹ At the hearing on the motions to dismiss the private plaintiffs' Master Consolidated Complaint (the "MCC"), the Court further remarked, "[y]ou've got to meet 9(b) requirements. You've got to particularize exactly what drugs, exactly what the fraud is, which plaintiffs paid for what drugs." Transcript of January 12, 2003 Hearing at 74. Amgen was one of only seven defendants subsequently dismissed entirely from the MCC.

Exhibit A to the amended complaint identifies three Amgen products: EPOGEN®, Neupogen®, and Enbrel®. AC at ¶25 and Exhibit A. The Court, at a minimum, should dismiss any asserted claim for unidentified "Covered Drugs" not specifically identified in the amended complaint.

² Fed. R. Civ. P. 9(b) provides that, "[i]n all averments of fraud, ...the circumstances constituting the fraud... shall be stated with particularity." Because allegations of fraud are at the core of each of plaintiffs' claims against Amgen, they are subject to Rule 9(b). See *Hayduk v. Lanna*, 775 F.2d 441, 443 (1st Cir. 1985) (quoting *Lopez v. Bulova Watch Co., Inc.*, 582 F. Supp 755, 766 (D.R.I. 1984)). Whatever the nature of the specific cause of action asserted, this Circuit applies Rule 9(b) where those claims sound in fraud. See, e.g., *Hayduk*, 775 F.2d at 443; *McGinty v. Beranger Volkswagen, Inc.*, 633 F.2d 226, 228-29 (1st Cir. 1980); *Arruda v. Sears, Roebuck & Co.*, 310 F.3d 13, 18-19 (1st Cir. 2002); *Boston & Maine Corp. v. Town of Hampton*, 987 F. 2d. 855, 865-66 (1st Cir. 1993).

³ Suffolk's reference to the OIG's 1993 Report on EPOGEN® reimbursement is unavailing. (AC at ¶¶ 141). That study, which was conducted as part of HHS' consideration of whether changes were needed to the reimbursement methodology, did *not* find or even suggest that Amgen's rebates were in any way improper. Indeed, as HCFA's comments to the report noted, "[HCFA] believes that the elimination of rebates . . . would not result in a change in the manufacturer's price, nor would it serve any program end." Further, as noted below, reimbursement for EPOGEN® under Medicare Part B is not even based on AWP. Consequently, the very premise for which Suffolk cites this report (*i.e.*, that these rebates somehow widen the gap between actual cost and AWP) is faulty.

- o used “other impermissible inducements” -- not one of which is identified in any way (much less with specificity) -- to stimulate sales of its products (AC at ¶ 140).⁴

Even assuming that Suffolk adequately makes out a scheme to defraud, the absence of any specifics as to Amgen’s supposed role requires dismissal under Rule 9(b). *See, e.g., Curtis v. Duffy*, 742 F. Supp. 34, 38 (D. Mass. 1990)(not enough to “salt the complaint with the words ‘falsely’ and ‘fraudulently’”); *United States ex rel. Clausen v. Laboratory Corp. of America.*, 290 F.3d 1301, 1311 (11th Cir. 2002) (detailed allegations of general scheme to defraud, without allegations of specific actions by the defendant, does not comply with Rule 9(b)); *United States ex rel. Barmak v. Sutter Corp.*, 2003 WL 21436213, *4-5 (S.D.N.Y. June 20, 2003) (same).

Suffolk repeatedly relies on sweeping allegations against the entire pharmaceutical industry, casting manufacturers together under the convenient rubric “defendants” or “pharmaceutical manufacturers” rather than providing specifics to support its claims. *See, e.g.,* AC at ¶ 2 (“For the last decade, defendants have engaged in a systematic and pervasive fraudulent scheme with others in the pharmaceutical distribution chain . . . to collect inflated prescription drug payments from Suffolk”); *see also* AC at ¶¶ 4, 7, 8, 10, 13, 14, 16, 17. Rule 9(b), however, requires particularized factual allegations as to *each* defendant. *See, e.g., Romani v. Shearson Lehman Hutton*, 929 F.2d 875, 877-78 (1st Cir. 1991). Plaintiffs’ efforts to paint defendants with one brush is nowhere more clear than in Suffolk’s baseless and flatly incorrect allegation that *all* “defendants” have been the subject of investigations by DOJ, OIG, GAO or unidentified Congressional Committees for “questionable practices regarding the industry’s

⁴ Suffolk’s best price allegations, based in part upon the alleged failure to disclose “discounts, free samples and other inducements,” also fail under Rule 9(b) because Suffolk provides no specifics regarding any such “unlawful” inducements and because Suffolk fails altogether to identify a single allegedly fraudulent Best Price for any Amgen product or any corresponding “correct” Best Price. *See LaCorte v. Merck & Co., et al.*, No. 99-3807, slip op. at 6 (E.D. La. Aug. 27, 2003).

calculation of AWP's and for offering illegal incentives to providers." AC at ¶ 108. This allegation, as to Amgen, is patently false. Indeed, and unlike its allegations against other manufacturers, Suffolk is unable to allege that Amgen is or has been the subject of any such investigation, audit, or similar inquiry. *Compare* AC at ¶¶ 138-145 (allegations against Amgen) with AC at ¶¶ 150-51, 163, 175-79, 198-200, 222, 234-244, 255, 272-77, 293-96, 304 (allegations of governmental investigations against others).⁵

Many of Suffolk's factual allegations are based on nothing more than information and belief and, as such, are wanting. *See, e.g.*, AC at ¶ 16 ("Suffolk alleges upon information and belief that, in many instances, the AWP reported by the defendant pharmaceutical manufacturers bears a minimal relationship to the prices actually paid by providers and is 'made up' ..."). *See Wayne Inv., Inc. v. Gulf Oil Corp.*, 739 F.2d 11, 13 (1st Cir. 1984); *United States ex rel. Walsh v. Eastman Kodak Co.*, 98 F. Supp. 2d 141, 148 (D. Mass. 2000) (Saris, J.) (quoting *In re Boston Tech., Inc. Sec. Litig.*, 8 F. Supp. 2d 43, 53 (D. Mass. 1998) ("the First Circuit looks cautiously upon plaintiffs alleging fraud purely on the basis of information and belief"). In fact, the entirety of Suffolk's allegations that Amgen reported inflated AWP's prior to 2001 are based on information and belief. *See* AC at ¶ 139.

Likewise, Suffolk cannot base its pleading on a mere suspicion of fraud in the hope that it can uncover facts later to support its hunch. (*See* AC at ¶¶ 143-144) (conceding that the specifics of "Amgen's promotional, discounting and pricing practices" and the "facts surrounding Amgen's discounting and rebate activities" are unknown to it and must be "revealed

⁵ Suffolk's efforts, in ¶ 116 of the Amended Complaint, to link Amgen to a September 2000 GAO report underscores the lack of care it exercised in drafting this pleading. The report does not, as Suffolk implies, mention Amgen (or Johnson & Johnson, for that matter) by name, and in fact refers only to "epoetin alpha [sic] for non-ESRD." Epoetin alfa for non-ESRD uses is marketed and sold exclusively by Johnson & Johnson as Procrit® and is neither marketed nor sold by Amgen.

through discovery”). This type of pleading is precisely the kind of improper “fishing expedition” that Rule 9(b) is designed to prevent. *See, e.g., U.S. ex rel. Franklin v. Parke-Davis*, 147 F. Supp. 2d 39, 46 (D. Mass. 2001) (Saris, J.) (citing *New England Data Servs. v. Becher*, 829 F.2d 286, 292 (1st Cir. 1987)) (Rule 9(b) serves to “prevent[] conclusory allegations of fraud from serving as a basis for strike suits and fishing expeditions, and [to] protect[] defendants from groundless charges that may damage their reputations”). At the end of the day, and despite its length, Suffolk’s amended complaint provides no specifics to support its contention that the AWP for any Amgen product is fraudulent. Simply saying that a published AWP is “false” does not make it so. Rule 9(b) and this Court’s directives require more. *See Suna v. Bailey Corp.*, 107 F.3d 64, 68 (1st Cir. 1997).⁶

II. Suffolk’s Claims Based On EPOGEN® Should be Dismissed.

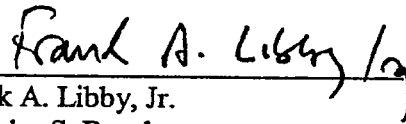
Reimbursement under both Medicare and Medicaid for Amgen’s product, EPOGEN®, is not based on AWP, but is instead set at a statutory rate under both Medicare and Medicaid (\$10 per 1,000 units administered) that has remained unchanged for nearly a decade. *See* 42 U.S.C. § 1395rr(b)(11)(B). Unlike any other product identified in the amended complaint, the reimbursement rate set by Congress, CMS, and New York State for EPOGEN® is both publicly available and widely known. Thus, whatever Amgen’s reported price for purposes of AWP, Suffolk thus cannot reasonably claim that it has been deceived into paying any falsely inflated payments for EPOGEN®.

⁶ Suffolk’s claims against Amgen should be dismissed without further leave to amend. Amgen should not be put to the further burden and expense of defending itself against such allegations where Suffolk has shown its inability to meet the threshold requirements of Rule 9(b). Dismissal with prejudice is particularly warranted where, as here, a plaintiff has had ample time to investigate its beliefs and its pleading makes clear that its claims are nothing more than unsupported suspicions. *See Hayduk*, 775 F.2d at 445; *Tapogna v. Egan*, 141 F.R.D. 370, 373 (D. Mass. 1992) (denying request for leave to amend because plaintiffs had already been given one opportunity to amend, they “had ample opportunity to allege any facts of which they were aware,” and the request amounted to nothing more than “a fishing expedition at the defendants’ expense”).

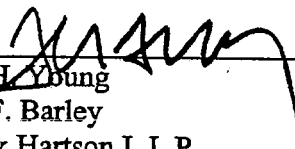
CONCLUSION

For the foregoing reasons, and for the reasons set forth in the defendants' joint motion and memorandum, Amgen requests that the amended complaint filed against it in this action be dismissed with prejudice.

Respectfully submitted,



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Dated: August 1, 2003

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UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

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In Re: PHARMACEUTICAL INDUSTRY
AVERAGE WHOLESALE PRICE
LITIGATION

:
: MDL NO. 1456
:
: Master File No. 01-CV-12257-PBS
:

THIS DOCUMENT RELATES TO:
County of Suffolk v. Abbott Labs, Inc. et al.,
03-CV-10643-PBS
----- x

: Judge Patti B. Saris
:

**MEMORANDUM OF LAW IN SUPPORT
OF ASTRAZENECA PHARMACEUTICALS LP'S
MOTION TO DISMISS THE AMENDED COMPLAINT**

AstraZeneca Pharmaceuticals LP ("AstraZeneca")¹ respectfully submits this memorandum of law in further support of its motion to dismiss the County of Suffolk's Amended Complaint ("Amended Complaint"). For the reasons set forth below and in defendants' consolidated memorandum of law ("Consolidated Memorandum"), the claims against AstraZeneca should be dismissed.

ALLEGATIONS OF THE AMENDED COMPLAINT

In the Amended Complaint, Suffolk County asserts a variety of federal and state claims against AstraZeneca, based on two types of alleged misconduct: 1) the fraudulent reporting of false and inflated average wholesale prices ("AWPs") for certain drugs; and 2) the failure to report the "best price" for certain drugs, as required by the federal Medicaid Rebate statute. Amended Complaint ("Am. Compl.") ¶ 2. Suffolk County further alleges that as a result of AstraZeneca's alleged misconduct, it paid inflated charges for three AstraZeneca drugs: Nexium,

¹ The entity identified in the complaint as AstraZeneca US does not exist. Although mentioned in the complaint, AstraZeneca PLC is not a defendant in this action.

Prilosec and Seroquel. Am. Compl. ¶¶ 26, 146, Ex. A-B. No other AstraZeneca drugs are identified on Suffolk County's list of alleged Medicaid overcharges, *see* Am. Compl. Ex. A, or on Suffolk County's list of top 2001 Medicaid pharmacy costs, *see* Am. Compl. Ex. B. Moreover, with respect to the three drugs that are identified, the only allegations contained in the Amended Complaint are two isolated data points from one year: the reported AWP in 2001 and Suffolk County's "estimated true AWP" for the same year. Am. Compl. ¶ 146, Ex. A. No where in the Amended Complaint is the methodology or underlying data for this latter number revealed.

ARGUMENT

PLAINTIFF'S FRAUD-BASED CLAIMS AGAINST ASTRAZENECA MUST BE DISMISSED PURSUANT TO RULE 9(B)

A plaintiff must plead the "who, what, where and how" of an alleged fraud in order to satisfy Rule 9(b) of the Federal Rules of Civil Procedure. *See United States ex rel. Franklin v. Parke-Davis*, 147 F. Supp. 2d 39, 46 (D. Mass. 2001). Moreover, in the similar context of defendants' motions to dismiss the Master Consolidated Class Action Complaint, this Court held that plaintiffs must also allege "the allegedly fraudulent AWP for each drug" in order to state a claim with respect to that drug. *In re Pharmaceutical Indus. Average Wholesale Price Litig.*, 263 F. Supp. 2d 172, 194 (D. Mass. 2003). Suffolk County fails to satisfy these standards in the Amended Complaint with respect to any drug manufactured by AstraZeneca. Accordingly, all fraud-based claims against AstraZeneca in the Amended Complaint – whether based on an AWP or Best Price theory – must be dismissed.

Suffolk County fails to allege any particularized facts relating to Prilosec, Nexium and Seroquel, much less any facts, which, if proven, would constitute fraud. Instead, plaintiff fills

three pages of its Amended Complaint with allegations relating to Zoladex, another drug manufactured by AstraZeneca. Am. Compl. ¶¶ 150-58. However, Suffolk County does not allege that it incurred any costs with respect to Zoladex²; instead, these allegations appear in the Amended Complaint solely as an “example” of “the ways in which AstraZeneca wrongfully and falsely has inflated” its reported AWP. Am. Compl. ¶ 152.

Fraud cannot be plead by example. Plaintiff’s allegations regarding Zoladex are simply not relevant to its claims regarding Nexium, Prilosec and Seroquel. And since there are no other particularized allegations supporting these claims, they must be dismissed.

Suffolk County’s conclusory allegations of a purported “true AWP” (“Suffolk’s Estimated True AWP”), *see* Am. Compl. ¶ 146, do not alter this conclusion. There are simply no specific factual allegations in the Amended Complaint supporting this alleged “true AWP.” Although the Amended Complaint refers somewhat cryptically to Suffolk County’s “investigations,” not a single detail is provided as to the methodology or underlying data used to derive Suffolk County’s estimated AWP. Accordingly, Suffolk County fails to satisfy Rule 9(b) and all fraud-based claims in the Amended Complaint must be dismissed.³

² As noted above, there are no allegations in the Amended Complaint that Suffolk County incurred costs for any AstraZeneca drugs other than Nexium, Prilosec and Seroquel. *See* Am. Compl. Ex. A-B. Accordingly, at a minimum, Suffolk County’s suggestion that it has claims with respect to “all covered drugs manufactured by AstraZeneca,” Am. Compl. ¶ 147, must be rejected pursuant to Rule 9(b).

³ Suffolk County’s allegations of overcharges are also inaccurate. Exhibit A to the Amended Complaint calculates Suffolk County’s alleged overcharges on the basis of the reported AWP. However, as discussed in the Consolidated Memorandum, New York State reimburses for prescription drugs at AWP less 12%. Moreover, Suffolk County is only responsible for 25% of this amount.